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By Electronic Filing

April 11, 2017

Molly C. Dwyer
Clerk of Court
United States Court of Appeals for the Ninth Circuit
James R. Browning Courthouse
95 7th Street
San Francisco, CA 94103

Re: *United States ex rel. Jeffrey Campie and Sherilyn Campie, et al., v. Gilead Sciences, Inc.*; Case No. 15-16380

Dear Ms. Dwyer:

Pursuant to Federal Rule of Appellate Procedure 28(j) and Circuit Rule 28-6, Appellee Gilead Sciences, Inc. respectfully advises the Court of *D'Agostino v. ev3, Inc.*, 845 F. 3d 1 (1st Cir. 2016).

In *D'Agostino*, as in this case, the relator alleged that the medical device manufacturer made fraudulent representations to the FDA, failed to disclose required information to the FDA, and made adulterated and unsafe medicines available to the public. Just like the District Court in this case, the First Circuit found that neither FDA approval nor the alleged misrepresentations and manufacturing defects was a material precondition of payment under the False Claims Act.

Citing the Supreme Court's decision in *Universal Health Services, Inc. v. Escobar*, 136 S.Ct. 1989 (2016), the First Circuit held that "[t]he FDA's failure actually to withdraw its approval of [the device] in the face of [relator]'s allegations precludes [him] from resting his claims on a contention that the FDA's approval was fraudulently obtained." 845 F. 3d at 8. The Court also relied on the undisputed fact that CMS continued to reimburse for the device for years even after learning of relator's allegations. Finally, the First Circuit found that "[i]n the six years since [relator] surfaced the alleged fraud," the FDA never exercised its varied and broad regulatory authority, including the agency's power to withdraw approval and order recalls and relabeling. The Court further found that a contrary ruling would "turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." *Id.*

The reasoning of *D'Agostino* further supports affirmance of the dismissal below.

Respectfully submitted,

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s/ Gretchen Hoff Varner

Gretchen Hoff Varner

CERTIFICATE OF SERVICE

I hereby certify that on April 11, 2017, I electronically filed the attached Rule 28(j) letter with the Clerk of the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served on the appellate CM/ECF system, and other parties will be served via electronic means:

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Dated: April 11, 2017

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By s/Gretchen Hoff Varner